Final

Permit Application Submitted to: Nebraska Department of Environmental Quality

Prepared for

BD Medical - Pharmaceutical Systems

605 East 23rd Street
Columbus, Nebraska

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Acronyms

°C	Degrees Celsius
°F	Degrees Fahrenheit
BACT	Best Available Control Technology
CFR	*Code of Federal Regulations*
CO	Carbon Monoxide
EPA	Environmental Protection Agency
EtO	Ethylene Oxide
ft^3	Cubic Feet
HAP	Hazardous Air Pollutant
hp	Horsepower
hrs/yr	Hours per Year
kW	Kilowatt
LAER	Lowest Achievable Emission Rate
lbs	Pounds
lbs/yr	Pounds per Year
LEL	Lower Explosive Limit
MACT	Maximum Available Control Technology
MSDS	Material Safety Data Sheet
NDEQ	Nebraska Department of Environmental Quality
NESHAP	National Emission Standards for Hazardous Air Pollutants
NO_X	Nitrogen Oxide
NSPS	New Source Performance Standards
PM_{10}	Particulate Matter Less than 10 Microns
ppm	Part per Million
RACT	Reasonable Achievable Control Technology
scfh	Standard Cubic Feet per Hour
SO_2	Sulfur Dioxide

tpy	Tons per Year
VOC	Volatile Organic Compound

1.0 Introduction

BD Medical - Pharmaceutical Systems located in Columbus, Nebraska, is submitting this application to secure an amendment to the current construction permit to add a proposed new four-chamber ethylene oxide (EtO) sterilizer unit and one new emergency power generator. **BD Medical** - Pharmaceutical Systems is not a major source of air emissions under Title V; however, the new EtO unit is subject to National Emission Standards for Hazardous Air Pollutants (NESHAP); therefore **BD Medical** - Pharmaceutical Systems is required to apply for a Title V operating permit for the EtO unit. However, the submittal of Title V operating permit applications have been deferred until December 2005, and the Environmental Protection Agency (EPA) has proposed elimination of the Title V permit requirement. A Title V operating permit application is not included in this package based on discussions with the Nebraska Department of Environmental Quality (NDEQ) on January 18, 2005.

2.0 Process Description

BD Medical - Pharmaceutical Systems is a medical device manufacturing plant located in Columbus, Nebraska. The plant manufactures hypodermic syringes and prefillable drug-delivery systems for pharmaceutical companies.

2.1 Ethylene Oxide Sterilizer

BD Medical - Pharmaceutical Systems is proposing the addition of a new EtO sterilization unit capable of terminally sterilizing all medical devices, plastic goods, and instruments manufactured at **BD Medical** - Pharmaceutical Systems. The unit will include four chambers. The chambers will be constructed of steel with a stainless steel interior and will employ a hot water jacket. A gas dispensing/steam injection system will be employed to ensure sufficient distribution of EtO gas and steam in the chambers. The steam to the chambers will be provided from two existing natural gas boilers discussed below. Inert gas (nitrogen) will be used to purge the chambers before the EtO gas introduction. The expected maximum EtO usage for the system is 455,855 pounds per year (lbs/yr). The sterilization system will be manufactured by Getinge UK Ltd.

A catalytic oxidation system will be used to control EtO emissions from the sterilization unit. The system will include a LESNI A/S Compact tower packed absorber type unit, with integral column, sump tank, and a low-temperature catalytic oxidation system. The EtO stream is pulled into the balancer tank that normalizes the concentration to the oxidizer, diluted with heated ambient air from the hot box (aeration room), and oxidized in presence of a catalyst bed. The maximum EtO concentration to the catalyst will be 25 percent of the Lower Explosive Limit (LEL). The LEL for EtO is 3 percent by volume in air. The catalyst will have at least 99.9 percent removal efficiency. Documentation of the control system removal efficiency is provided in Appendix C. The exhaust from the catalyst will be vented to the atmosphere through a 52-foot stack. The expected air flow from the system is 7,060 cubic feet (ft^3) per minute with an exit temperature ranging from 55 degrees Celsius (°C) to 135 °C.

2.2 Emergency Generator

A 600 kilowatt (kW) diesel generator will be added to the facility as part of this project. The generator will be operated with low sulfur content diesel fuel for no more than 300 hours per year.

2.3 Construction Schedule

The construction for the EtO project will commence upon issuance of the construction permit. The construction of the first chamber with the control system is expected to be completed in May 2007. The first chamber will start operation in June 2007. **BD Medical** - Pharmaceutical Systems will submit a notification letter to NDEQ upon startup of the

first chamber. Each chamber will be installed one at a time and will be phased into the control system. For each chamber, **BD Medical** - Pharmaceutical Systems will submit a notification letter upon commencement of construction, completion of construction and startup of the chambers. A construction schedule for the chambers has not been developed at this time.

3.0 Emissions Summary

An emergency generator and an EtO sterilization unit will be added to the facility as part of this project. As discussed in Section 2 of this application, a catalytic oxidizer will be added to reduce EtO emissions from the sterilizer. Two existing New Source Performance Standards (NSPS)-regulated boilers (source ID 58-1 and 59-1) will be used to provide steam to the EtO sterilization unit. The potential to emit (PTE) for both boilers are estimated based on 8,760 hours per year operation in the current construction permit. Therefore, emissions for the boilers are not included in this section. This section provides a summary of emissions from the proposed sources.

3.1 Emergency Generator

An emergency generator with a rating of 600 kW will be added to the facility. The generator will be operated for a maximum of 300 hours per year. Emissions for criteria pollutants for the generators are estimated using factors from AP-42, Fifth Edition, Table 3.4-1. Hazardous Air Pollutant (HAP) emissions are estimated using factors from AP-42, Fifth Edition, Tables 3.4-3 and 3.4-4. The emissions are summarized in Tables 3-1 and 3-2. Detailed emission calculations are provided in Appendix C.

TABLE 3-1
Generator – Criteria Pollutant Emissions

	Generator
Engine Rating (kW)	600
Engine Rating (horsepower [HP])	805
Hours of Operation (hours per year [hrs/yr])	300
Nitrogen Oxide (NO_X) Emissions (tons per year [tpy])	1.57
Carbon Monoxide (CO) Emissions (tpy)	0.66
Particulate Matter Less than 10 Microns (PM_{10}) Total Emissions (tpy)	0.08
Sulfur Dioxide (SO_2) Emissions (tpy)	0.05
Volatile Organic Compound (VOC) Emissions (tpy)	0.09

TABLE 3-2
Generator – Hazardous Air Pollutant Emissions

Pollutant	Generator Emissions (lb/yr)
Benzene	4.76E-01
Toluene	1.72E-01
Xylenes	1.18E-01
Propylene	1.71E+00
Formaldehyde	4.84E-02
Acetaldehye	1.55E-02
Acrolein	4.83E-03
Naphthalene	7.97E-02
Acenaphthylene	5.66E-03
Acenaphthene	2.87E-03
Fluorene	7.85E-03
Phenanthrene	2.50E-02
Anthracene	7.54E-04
Fluoranthene	2.47E-03
Pyrene	2.27E-03
Benz(a)anthracene	3.81E-04
Chrysene	9.38E-04
Benzo(b)fluoranthene	6.81E-04
Benzo(k)fluoranthene	1.34E-04
Benzo(a)pyrene	1.58E-04
Indeno(1,2,3-cd)pyrene	2.54E-04
Dibenz(a,h)anthracene	2.12E-04
Benzo(g,h,l)perylene	3.41E-04

3.2 EtO Sterilizer/Lesni

The EtO sterilizer will be equipped with a control device that will include a tank and a catalytic oxidizer to destroy EtO emissions from the unit. The oxidizer will have a removal efficiency of 99.9 percent. The LEL for EtO is provided in its Material Safety Data Sheet (MSDS), which is provided in Appendix C.

The annual EtO usage in the unit is expected to be 455,855 pounds (lbs). Assuming all the EtO used will result in emissions, the controlled EtO emissions to the atmosphere are estimated to be 456 lbs/yr. Detailed emission calculations are provided in Appendix C.

Natural gas will be used to maintain the temperature of the catalyst bed. Emissions for criteria pollutants are estimated using factors from AP-42, Fifth Edition, Tables 1.4-1 and 1.4-2. HAP emissions are estimated using factors from AP-42, Fifth Edition, Tables 1.4-3 and 1.4-4. The emissions from natural gas combustion are summarized in Tables 3-3 and 3-4.

TABLE 3-3
Lesni – Criteria Pollutant Emissions

	Lesni
Natural Gas Consumption (standard cubic feet per hour [scfh])	1,440
Annual Hours of Operations (hrs/yr)	8,760
NO_X Emissions (tpy)	0.32
CO Emissions (tpy)	0.53
PM Total Emissions (tpy)	0.05
SO_2 Emissions (tpy)	0.004
VOC Emissions (tpy)	0.03

TABLE 3-4
Lesni – Hazardous Air Pollutant Emissions

Pollutant	**Lesni Emissions (lb/yr)**
2-Methylnaphthalene	3.03E-04
3-Methylchloranthene	2.27E-05
7,12-Dimethylbenz(a)anthracene	2.02E-04
Acenaphthene	2.27E-05
Acenaphthylene	2.27E-05
Anthracene	3.03E-05
Benza(a)anthracene	2.27E-05
Benzene	2.65E-02
Benzo(a)pyrene	1.51E-05
Benzo(b)fluoranthene	2.27E-05
Benzo(g,h,I)perylene	1.51E-05
Benzo(k)fluoranthene	2.27E-05
Butane	2.65E+01

TABLE 3-4 (CONTINUED)
Lesni – Hazardous Air Pollutant Emissions

Pollutant	Lesni Emissions (lb/yr)
Chrysene	2.27E-05
Dibenzo(a,h)anthracene	1.51E-05
Dichlorobenzene	1.51E-02
Ethane	3.91E+01
Fluoranthene	3.78E-05
Fluorene	3.53E-05
Formaldehyde	9.46E-01
Hexane	2.27E+01
Indeno(1,2,3-cd)pyrene	2.27E-05
Naphthalene	7.69E-03
Pentane	3.28E+01
Phenanathrene	2.14E-04
Propane	2.02E+01
Pyrene	6.31E-05
Toluene	4.29E-02
Arsenic	2.52E-03
Barium	5.55E-02
Beryllium	1.51E-04
Cadmium	1.39E-02
Chromium	1.77E-02
Cobalt	1.06E-03
Copper	1.06E-02
Manganese	4.79E-03
Mercury	3.28E-03
Molybdenum	1.39E-02
Nickel	2.65E-02
Selenium	3.03E-04
Vanadium	2.90E-02
Zinc	3.66E-01
Lead	6.31E-03

4.0 Regulatory Review

This section provides a regulatory review of the applicability of state and federal air quality permitting requirements for the EtO sterilizer proposed by **BD Medical** - Pharmaceutical Systems.

4.1 State of Nebraska Air Permitting Requirements

Nebraska-specific air quality regulations are found in Title 129 of the Nebraska Administrative Code.

4.1.1 Construction Permits (Title 129 Chapter 17)

The addition of the EtO sterilizer, boilers, and an emergency generator will result in an increase of some air pollutant emissions, necessitating the issuance of a construction permit pursuant to Title 129 Chapter 17- Construction permits. **BD Medical** - Pharmaceutical Systems is required by Title 129 Chapter 17, Section 001 to submit to NDEQ this construction permit application and obtain an NDEQ-issued construction permit prior to initiation of construction activities associated with the proposed project.

4.1.2 Operating Permit Requirements (Title 129, Chapter 5)

The federal operating permits program (Title V) is implemented by regulations codified at 40 *Code of Federal Regulations (CFR)* Parts 70 and 71. The State of Nebraska has been granted authority to implement and enforce the federal Title V program through state regulations outlined under Title 129, Chapter 5. Chapter 5, Section 001.01C states that any source, including an area source, subject to a standard or other requirement under Chapter 28 (rule which incorporates NESHAP standards) is required to obtain an operating permit. The proposed EtO sterilizer emissions are regulated under the NESHAP program, therefore, **BD Medical** - Pharmaceutical Systems would be required to obtain a Title V operating permit for the proposed EtO sterilizer, but only with respect to those air pollutants that are regulated for this category (EtO). The EtO sterilizer is one of six categories of area sources which had Title V permit deferrals until December 9, 2004. Title V regulations establish a 1-year deadline (December 9, 2005) for the submittal of permit applications for these sources. However, the EPA is now in the process of finalizing a rulemaking action which may exempt some of these area sources from Title V. Therefore, the EPA has requested that permitting authorities wait until the final rule before requiring Title V permits for these sources.

4.1.3 Air Quality Impact Analysis (Title 129 Chapter 17, Section 008)

An Air Quality Impact Analysis is not deemed necessary as the increase in the emissions are below the modeling thresholds provided in the modeling guidance document.

4.1.4 Monitoring (Title 129 Chapter 34) and Reporting (Title 129 Chapter 6)

BD Medical - Pharmaceutical Systems will be subject to monitoring requirements as described in Title 129 Chapter 34 and reporting requirements as described in Title 129 Chapter 6.

4.1.5 HAP, Maximum Available Control Technology (Title 129 Chapter 27)

BD Medical - Pharmaceutical Systems will be subject to the Maximum Available Control Technology (MACT) and Best Available Control Technology (BACT) requirements as described in Title 129, Chapter 27. The analysis is provided in Section 5.0 of this permit application.

4.2 Federal Air Quality Regulations: NESHAPS (40 *CFR* Part 63 Subpart O)

The proposed EtO unit at **BD Medical** - Pharmaceutical Systems is subject to the NESHAP for EtO commercial sterilization operations as described in 40 *CFR* Part 63 Subpart O. This rule describes applicability, standards, compliance and performance testing, monitoring requirements, test methods and procedures, reporting, and recordkeeping requirements.

4.2.1 General Provisions Applicability to Subpart O

The proposed EtO unit at **BD Medical** - Pharmaceutical Systems will be using greater than 10 tons of EtO in any 12-month period. Table D-1 (Appendix D) lists the general provisions of 40 *CFR* Part 63 Subpart A which are applicable to sources using 10 tons or more of EtO in any 12-month period as described in 40 *CFR* 63.360. Within the general provisions of Subpart A are requirements for applicability, definitions, units and abbreviations, prohibited activities, preconstruction review, compliance with standards and maintenance, performance testing, monitoring, notification, recordkeeping and reporting, control device, state authority and delegations, addresses of the EPA, and availability of information and confidentiality.

4.2.2 Standards: 40 *CFR* 63.362

The new EtO unit is subject to the standards described in 40 *CFR* 63.362 for sources using greater than 10 tons of EtO. This standard requires 99 percent emission reduction for sterilization chamber vents, and 1 part per million (ppm) maximum outlet concentration or 99 percent emission reduction, whichever is less stringent, from each aeration room vent.

4.2.3 Compliance and Performance Provisions: 40 *CFR* 63.363

The new EtO unit sterilization chamber vents are subject to the compliance and performance provisions described in 40 *CFR* 63.363(a)-(b) and (f). Part (a) of this section requires compliance with the requirements of 40 *CFR* Part 63 Subpart A. Part (b) of this section describes initial performance test requirements to be used for determining initial compliance with emission limits (99 percent reduction) and establishment of operating

limits for the catalytic oxidizer. The catalytic oxidizer operating limit consists of the recommended minimum oxidation temperature provided by the manufacturer. 40 *CFR* 63.363(b)(4) details three work practice compliance options for replacement of the catalyst bed. Part (f) requires a facility demonstrate continuous compliance with operating limits and work practices except during startup, shutdown, and malfunction.

The aeration room vents are subject to the compliance and performance provisions described in 40 CFR 63.363 (a), (c) and (f). The requirements of part (a) and (f) are described above. The initial compliance test for the catalytic oxidizer are the same as those for the chamber vents in 40 CFR 63.363 (b)(2) and (3). Part (c) requires determination of EtO concentration emitted to the atmosphere after the control device (1 ppm limit) or determination of the efficiency of the control device (99 percent reduction).

4.2.4 Monitoring Requirements: 40 *CFR* 63.364

The new EtO unit is subject to the monitoring requirements described in 40 *CFR* 63.364(a), (c), and (e). Part (a) of this section requires compliance with the requirements of 40 *CFR* Part 63 Subpart A. There are two options for monitoring the catalytic oxidation unit as detailed in 40 *CFR* 63.364(c) and (e): either, (1) continuously monitor and record oxidation temperature at the outlet to the catalyst bed or (2) measure and record once per hour the EtO concentration at the outlet to the atmosphere.

4.2.5 Test Methods and Procedures: 40 *CFR* 63.365

The new EtO unit is subject to the test methods and procedures described in 40 *CFR* 63.365(a)-(c). Part (a) of this section requires compliance with the requirements of 40 *CFR* Part 63 Subpart A. 40 *CFR* 63.365(b) describes the method to be used to determine the efficiency of control devices used to comply with the sterilization chamber vent standard. 40 *CFR* 63.365(c) describes the testing methods used to determine EtO concentration; 63.365(c)(1) describes parameter monitoring required for the catalytic oxidation system and 63.365(c)(2) describes initial compliance test methods for the aeration room vent standard.

4.2.6 Reporting Requirements: 40 *CFR* 63.366

The new EtO unit is subject to the reporting requirements in 40 *CFR* 63.365. Part (a) of this section requires compliance with the requirements of 40 *CFR* Part 63 Subpart A. This section includes notification and application requirements for construction and reconstruction of facilities.

4.2.7 Recordkeeping Requirements: 40 *CFR* 63.367

The new EtO unit is subject to the recordkeeping requirements in 40 *CFR* 63.367(a) and (d). Part (a) of this section requires compliance with the requirements of 40 *CFR* Part 63 Subpart A. Part (d) of this section requires maintenance of compliance test, data analysis, and catalyst replacement records for the oxidation catalyst.

5.0 Control Technology Analysis

This section describes the air pollution control equipment that will be utilized on the proposed EtO sterilization chamber vent, natural gas boilers, and emergency generator. The BACT analysis has been prepared for all pollutants from the EtO sterilization chamber vent and generator.

5.1 EtO Sterilization Chamber Vents

The EPA's Reasonable Achievable Control Technology (RACT)/BACT/Lowest Achievable Emission Rate (LAER) Clearinghouse was reviewed to identify potential control technologies for EtO control on sterilization chamber vents. The results of this review are provided in Appendix B. Only one control technology has been identified for EtO control: Catalytic Oxidizer.

The EtO stream is pulled into the balancer tank that normalizes the concentration to the oxidizer, diluted with heated ambient air from the hot box, and oxidized in presence of a catalyst bed. The inlet EtO concentrations are diluted to prevent catalyst bed temperatures from increasing over about 500 degrees Fahrenheit (°F) due to the exothermic reaction. Because of its high removal efficiency (99.9 percent) over a wide range of inlet concentrations, catalytic oxidation can be used to control sterilization chamber vent exhaust streams.

Catalytic oxidation is the most effective control technology available and is technically feasible for this project.

BD Medical - Pharmaceutical Systems is proposing catalytic oxidation with 99.9 percent control for EtO emissions from the project. Since the top technology has been selected, an economic and energy analysis is not required. Catalytic oxidation is BACT for this project.

5.2 Emergency Generator

A diesel-fired emergency generator with a rating of 600 kW will be added to the facility as part of this project. A search of the EPA's RACT/BACT/LAER Clearinghouse database shows that BACT for generators this size is no add-on controls and good combustion practices. The results of this review are provided in Appendix B. The proposed generator will be operated with low-sulfur diesel fuel to reduce emissions. The generator will be operated in accordance with manufacturer's recommendations and good combustion practices. Good combustion practices are identified as BACT for the emergency generators.

6.0 Monitoring Information/Permit Limits

6.1 Monitoring Information

This section describes the monitoring devices and activities as well as the test methods used for determining compliance.

Monitoring Devices

The following compliance monitoring devices will be used:

- Catalytic Oxidation System
  - A continuous monitor to measure the oxidation temperature at the outlet to the catalyst bed (63.364(c))

Monitoring Activities

The following monitoring activities will be performed:

- Catalytic Oxidation System
  - From 15-minute or shorter period temperature values, the data acquisition system for the temperature monitor will compute and record a daily average oxidation temperature (63.364(c))

Test Methods

The following test methods will be used for performance testing and to determine the mass of EtO emitted from the control device:

- The flow rate through the catalytic oxidizer will be measured by the procedure in 40 *CFR* Part 60, Appendix A, Test Methods 2, 2A, 2C, or 2D (or equivalent method approved by Executive Secretary)
- Test Method 18 or 25A will be used to measure the EtO concentration (or equivalent method approved by Executive Secretary)

6.2 Requested Permit Limit

Generators

The new diesel generator shall not exceed 12 operating hours per any period of 12 consecutive calendar months for testing purposes.

Boilers

Two existing NSPS regulated boilers, source IDs 58-1 and 59-1 are each limited to 3,000 hours per year operation. Since the PTE emissions in the current construction permit are based on 8,760 hours per year operation, **BD Medical** - Pharmaceutical Systems is requesting removal of operating limits on these two boilers.

7.0 References

Environmental Protection Agency (EPA). *Code of Federal Regulations.* Part 63.

EPA. RACT/BACT/LAER Clearinghouse Database.

EPA. *White Paper for Development of Part 70 Permit Applications*. July 10, 1995.

"Ethylene Oxide." Material Data Safety Sheet.

Nebraska Department of Environmental Quality. "Title 129." *Nebraska Administrative Code*.

APPENDIX A

Forms

FORM CS - COVER SHEET, CONSTRUCTION PERMIT APPLICATION

COMPANY/FACILITY NAME: **BD Medical -** Pharmaceutical Systems DATE: _____
FACILITY NUMBER: 73007

IMPORTANT: GENERAL INSTRUCTIONS ON THE BACK OF THIS FORM, PLEASE READ
Please indicate below the application forms and other data that are being included with this Construction Permit Application packet. All applications must include this completed cover sheet form.

- [a] [x] FORM 1.0 – General Information
- [a] [x] FORM 1.1 – Permit Application Fee
- [a] [x] FORM 1.2 – Process Diagram
- [a] [x] FORM 1.3 – Plant Layout Diagram
- [b] [x] FORM 2.0 – Process Information
- [c] [x] FORM 3.0 – Fuel Combustion Data
- [ ] FORM 4.0 – Asphalt Plant
- [ ] FORM 5.0 – Organic Liquid Storage
- [ ] FORM 6.0 – Incinerator
  - [d] [ ] Medical Waste Incinerator Permit Application
  - [d] [ ] General Permit Application – Incinerator
- [ ] FORM 7.0 – Grain Industry
- [ ] FORM 8.0 – Surface Coating Operations

- [a] [X] EMISSION CALCULATIONS:

  All references for emission factors must be completely documented (e.g., Compilation of Air Pollutant Emission Factors (AP42), Factor Information Retrieval (FIRE), Manufacturer, etc.). If FIRE is used, please provide the SCC code.

- [ ] SUPPLEMENTAL INFORMATION:
  - [ ] Check if air dispersion modeling data and results are included
  - [ ] Check if potential emissions are above Prevention of Significant Deterioration (PSD) levels.
  - [ ] Check if PSD information required by Chapter 19 is included.
  - [ ] Check if copies of manufacturer information/instructions are included.

  Other (Please List):_____

  _____

  _____

  _____

[a] Required for all permit applications.
[b] Form 2.0 must be submitted when Form 4.0 through Form 8.0 do not apply to the project.
[c] Form 3.0 must be submitted when fuel is combusted.
[d] Required for incinerators. See Form 6.0.

CONSTRUCTION PERMIT APPLICATION GENERAL INSTRUCTIONS

GENERAL INSTRUCTIONS

The following are general instructions for the completion and submittal of a Construction Permit Application. These instructions will not cover the individual Forms in this packet. Instructions for each Form are printed on the back of the form.

TIMELINESS

This application and additional information must be submitted to the Department of Environmental Quality at least 90 days prior to the anticipated date of the proposed construction, modification or reconstruction at a new or existing source, as per Title 129 - Nebraska Air Quality Regulations, Chapter 17. Your application must be reviewed and a permit must be granted before actual construction shall commence.

COMPLETENESS

All application packets must include: FORM CS - Cover Sheet; FORM 1.0 - General Information; FORM 1.1 - Permit Application Fee; FORM 1.2 - Process Diagram; and FORM 1.3 - Plant Layout Diagram. The other forms to be included in the application depend on the type of project that is being proposed. The Department has made process specific forms available, e.g., FORM 4.0 - Asphalt Plant, FORM 5.0 - Organic Liquid Storage, etc. In the event one of the process specific forms does not apply to the project, FORM 2.0 - Process Information must be submitted. Whenever fuel will be combusted as a result of the proposed project, FORM 3.0 - Fuel Combustion Data must be submitted.

Construction Permit Applications packets for incinerators must include the appropriate forms, as described above, and the appropriate Operating Permit Application form (Medical Waste Incinerator Permit Application or General Permit Application - Incinerator).

On each of the forms, the Department requests various types and amounts of information. This information is being requested to expedite the permitting process and to minimize the number of times the review engineer must contact the facility. Because of this, the information should be provided as completely and thoroughly as possible. If, in your opinion, a section does not apply to your project, you should enter NA in that section. Whenever NA is used, an explanation should be provided.

SUPPLEMENTAL INFORMATION

FORM CS includes a section where the user can indicate whether, or not, they have included supplemental information. In addition, other forms ask for any additional information pertinent to emission control such as flow rates, efficiency of control equipment, type of control equipment, performance standards, output loading, manufacturers guarantees, etc. Please include all additional information that will assist the review engineer in the assessment of the proposal. Whenever additional information is submitted, including an explanation as to why NA was used, it should be noted on FORM CS.

SUBMITTAL

Three copies of the completed Construction Permit Application must be submitted. All submittals must be forwarded to:

Department of Environmental Quality
Air Quality Permitting Section
P.O. Box 98922
Lincoln, NE 68509-8922

QUESTIONS

If you have any questions concerning any portion of the Construction Permit Application packet, please feel free to contact the Air Quality Permitting Section at (402) 471-2189 or the Environmental Assistance Division at their toll free number (877) CLEAN03 (253-2603).

INSTRUCTIONS: FORM 1.0 - GENERAL INFORMATION

1. **COMPANY/FACILITY NAME, STREET ADDRESS, MAILING ADDRESS, CITY STATE, ZIP AND NDEQ FACILITY ID#**: Enter the legal name and address of the company/facility as it is registered to do business in the state of Nebraska. In the case of national corporations, please provide the name and address of the parent corporation along with the name of it's Nebraska site (e.g., International Wrench, Inc., d.b.a. Nebraska Ratchet, etc.). Enter the Facility ID# if known.
2. **COMPANY/FACILITY LOCATION (IF OTHER THAN ABOVE):** For national corporations, please provide the location of the Nebraska site. For portable sources (e.g., asphalt plants, etc.), provide the initial location of where the source will operate within the State.
3. **COUNTY:** Enter the county where the company/facility is located and where the construction will take place. Provide legal description in space provided.
4. **INCORPORATION STATUS:** Indicate whether, or not, the business is incorporated, it's state of incorporation and the name and address of the Nebraska Registered Agent, if applicable.
5. **CONTACT PERSON:** Provide the name, and contact information, of the person to get in touch with in the event the NDEQ has questions concerning the application.
6. **NATURE OF BUSINESS:** Briefly describe the nature of the company/facility business. If manufacturing, indicate the final products produced.
7. **OPERATING SCHEDULE:** Indicate whether, or not, the source is operated seasonally. If so, provide the range in months that the source will be in operation each year (e.g., April-Oct., etc.). The hr/day, days/week, and weeks/year information must be provided in all cases.
8. **THIS APPLICATION IS FOR:** Indicate if the construction will be for a new source, or, if it is a modification or reconstruction of an existing source.
9. **EXISTING SOURCES:** Fill in the year that the source was originally constructed and the date that the construction permit was issued. Indicate (Y=Yes or N=No) if any modification has been made that increased air pollutant emissions. If any modification increased emissions, list the date of the modification, the date the construction permit was issued and provide a general description of the modification.
10. **PROJECTED DATE TO COMMENCE CONSTRUCTION, AND STARTUP:** Enter the projected date for when construction will begin (See Commence Construction definition below) and when the source is expected to begin operation.
11. **DESCRIPTION OF NEW OR MODIFIED PROCESS/EQUIPMENT**: Briefly describe the source operation(s) or facility you propose to construct or modify and indicate whether each proposed action is new construction or a modification of an existing source. Where appropriate include make and model of equipment, and if the equipment is new or used.
12. **ESTIMATED COST OF THE PROJECT/PROJECTED COST OF POLLUTION CONTROL EQUIPMENT**: Enter the estimated cost of the project and the pollution control equipment. This information is required to determine if the project is a modification or reconstruction of an existing source and/or to determine the applicability of emission standards.
13. **APPLICANTS CERTIFICATION STATEMENT:** Each application must include a certification statement indicating that the information contained in the application is true, accurate and complete and be signed by a Responsible Official of the organization that will operate the source, or by a Responsible Official of the organization which owns the source. A Responsible Official can be:
    a) For a corporation:
        i) A president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function; or,
        ii) Any other person who performs similar policy or decision-making functions for the corporation; or,
        iii) A duly authorized representative of such person if the representative is responsible for the overall operation of one or more manufacturing, production, or operating facilities applying for or subject to a permit and either:
            a) The facilities employ more than 250 persons or have gross annual sales or expenditures exceeding $25 million (in second quarter 1980 dollars); or,
            b) The delegation of authority to such representatives is approved in advance by the NDEQ.
    b) For a partnership of sole proprietorship:
        i) A general partner or the proprietor, respectively;
    c) For a municipality, State, Federal, or other public agency:
        i) Either a principal executive officer or ranking elected official. For the proposes of this application, the principal executive officer of a Federal agency included the chief executive officer having responsibility for the overall operations of a principal geographic unit of the agency (e.g., a Regional Administrator of EPA); or,
    d) For affected sources:
        i) The designated representative in so far as actions, standards, requirements, or prohibitions under Chapter 26, of Title 129, are concerned; and,
        ii) The designated representative for any other purposed under the Title V program.
14. Please include any additional information available for your proposed processes.

DEFINITIONS (Abbreviated definitions, see Title 129 for full definitions)

- Commence construction - When the owner or operator has all necessary preconstruction approvals and has: 1. Begun, or caused to begin, a continuous program of physical on-site construction; or, 2. Entered into binding agreements or contractual obligations, which cannot be canceled or modified without substantial loss to the owner or operator, to undertake construction of the source.
- Modification - Any physical change in, or change in method of operation of, a facility which increases the amount of any air pollutant.
- Reconstruction - A situation where the fixed capital cost of the new components exceeds 50 percent of the fixed capitol cost of a comparable entirely new facility or source. A reconstructed source will be treated as a new stationary source.

DUPLICATE THIS FORM AS NEEDED

DEPARTMENT OF ENVIRONMENTAL QUALITY
AIR QUALITY DIVISION
P.O. BOX 98922
LINCOLN, NE 68509-8922

NDEQ USE ONLY
TRACKING #
NDEQ FACILITY ID #
ASSIGNED TO:

CONSTRUCTION PERMIT APPLICATION
FORM 1.0 - GENERAL INFORMATION

IMPORTANT:INSTRUCTIONS ON BACK OF THIS FORM, PLEASE READ

COMPANY/FACILITY NAME:
BD Medical - Pharmaceutical Systems

COMPANY/FACILITY STREET ADDRESS:
605 East 23rd Street

COMPANY/FACILITY MAILING ADDRESS:
920 East 19th Street

COMPANY/FACILITY CITY:	STATE:	ZIP:	NDEQ FACILITY ID #:
Columbus	NE	68601	73007

COMPANY/FACILITY LOCATION (IF OTHER THAN ABOVE): STREET CITY
Same as Above

COUNTY: Platte
N 41 26'08.3" W 97 19'05.7"
TOWNSHIP: RANGE:

IS THE BUSINESS INCORPORATED? ☐ YES ☒ NO

IF YES, WHAT IS THE STATE OF INCORPORATION? STATE: ---

IF YES, WHO IS THE RESIDENT AGENT? NAME: ---

STREET CITY STATE ZIP

CONTACT PERSON: NAME
Gary Jacobs

PHONE:	FAX:	E-MAIL:
(402) 563-8286		gary_jacobs@bd.com

NATURE OF BUSINESS (PRODUCT MFG, POWER GENERATION, ETC.)
Medical Device Manufacturing

OPERATING SCHEDULE; SEASONAL: ☐ YES ☒ NO IF YES, GIVE RANGE:
HR/DAY DAYS/WEEK WEEKS/YEAR

THIS APPLICATION IS FOR:
☒ CONSTRUCTION OF A NEW SOURCE
☒ MODIFICATION OR RECONSTRUCTION OF AN EXISTING SOURCE

EXISTING SOURCES: WHAT YEAR WAS THE ORIGINAL FACILITY CONSTRUCTED? 2002 DATE PERMITTED? January 8, 2002
HAVE ANY MODIFICATIONS OCCURRED SINCE JUNE 6, 1972 WHICH INCREASED AIR POLLUTANT(S) EMISSIONS? ☐ Y ☐ N
IF YES, PLEASE PROVIDE A BRIEF SUMMARY OF EACH MODIFICATION BELOW (USE ADDITIONAL SHEETS IF NECESSARY).

DATE	DATE PERMITTED	SUMMARY OF MODIFICATIONS
	1/8/2002	Start of East Facility

PROJECTED DATE TO COMMENCE CONSTRUCTION:	PROJECTED DATE OF STARTUP:
August 2005	June 2007

DESCRIPTION OF NEW OR MODIFIED PROCESS/EQUIPMENT (PLEASE SUBMIT PLANS AND SPECIFICATIONS INCLUDING ANY EXPLANATORY MATERIALS) (USE ADDITIONAL SHEETS IF NECESSARY)
Addition of an ethylene oxide sterilizer with catalytic oxidizer as abatement system. Emergency generator will also be installed.

ESTIMATED COST OF PROJECT: $10.6M	ESTIMATED COST OF POLLUTION CONTROL EQUIPMENT:

APPLICANT'S CERTIFICATION STATEMENT

I CERTIFY, UNDER PENALTY OF LAW, THAT, BASED ON INFORMATION AND BELIEF FORMED AFTER REASONABLE INQUIRY, THE STATEMENTS AND INFORMATION CONTAINED IN THIS APPLICATION ARE TRUE, ACCURATE AND COMPLETE. I ALSO CERTIFY THAT THIS APPLICATION INCLUDES FORM CS AND ALL FORMS DENOTED ON FORM CS.

SIGNATURE (SEE BACK FOR SIGNATORY REQUIREMENTS) DATE (MM/DD/YY):

TYPED OR PRINTED NAME: TITLE:

DUPLICATE THIS FORM AS NEEDED

FORM 1.1 - PERMIT APPLICATION FEE

COMPANY/FACILITY NAME: **BD Medical -** Pharmaceutical Systems DATE:

NDEQ FACILITY ID#: 73007

Beginning January 1, 2005, each application for an Air Quality Construction Permit shall be accompanied by an application fee in accordance with State Statute 81-1505.06. The non-refundable application fee is based on the potential-to-emit (PTE) of the entire facility after processing the permit application. The application fee is not based on the PTE of the individual project. Please contact the Air Quality Permitting Section at 402-471-2189 with questions.

PERMIT APPLICATION FEE SCHEDULE

FACILITY-WIDE POTENTIAL-TO-EMIT	APPLICATION FEE
100 tons or more per year of any air pollutant; or 10 tons or more per year of any single hazardous air pollutant (HAP); or 25 tons or more per year of any combination of HAPs	$3,000
50 tons or more but less than 100 tons per year of any air pollutant; or 2.5 tons or more but less than 10 tons per year of any single HAPs; or 10 tons or more but less than 25 tons per year of any combination of HAPs	$1,500
Less than 50 tons per year of any air pollutant; or Less than 2.5 tons per year of any single HAP; or Less than 10 tons per year of any combination of HAPs	$250

Fee enclosed: $ 250

Make check payable to: Nebraska Department of Environmental Quality
Memo: Air Quality CP Application Fee

NOTE: If applying for a Permit-by-Rule (PbR) in accordance with Chapter 42, do not submit this form. Refer to the appropriate Notice of Intent form for remittance of the $250 PbR application fee.

NDEQ USE ONLY
AMOUNT PAID $
CHECK #:
RECEIPT #:

FORM 1.2 - PROCESS/FLOW DIAGRAM

COMPANY/FACILITY NAME: **BD Medical -** Pharmaceutical Systems DATE:

FACILITY ID#: 73007

Please provide a Process Diagram (Diagram) in the space below (Use back of this form and additional pages if necessary) or on a separate attached sheet(s). The Diagram is a flow chart that must include all processes, process equipment, stacks, air pollution control equipment, and fuel burning units identified in Forms 2.0 and 3.0, as appropriate. Process numbers and unit numbers must be cross referenced between this Diagram and the above Forms. When finished, this Diagram should show how products and materials (including fuel) flow through each process. Provide an inclusive date that the Diagram is accurate through. If a separate attached sheet(s) is (are) used (e.g., engineering diagrams, etc.), it (they) should be clearly marked as being a replacement for Form 1.2.

Please see enclosed attachment.

FORM 1.2 - PROCESS/FLOW DIAGRAM

ADDITIONAL DIAGRAM SPACE

DUPLICATE THIS FORM AS NEEDED

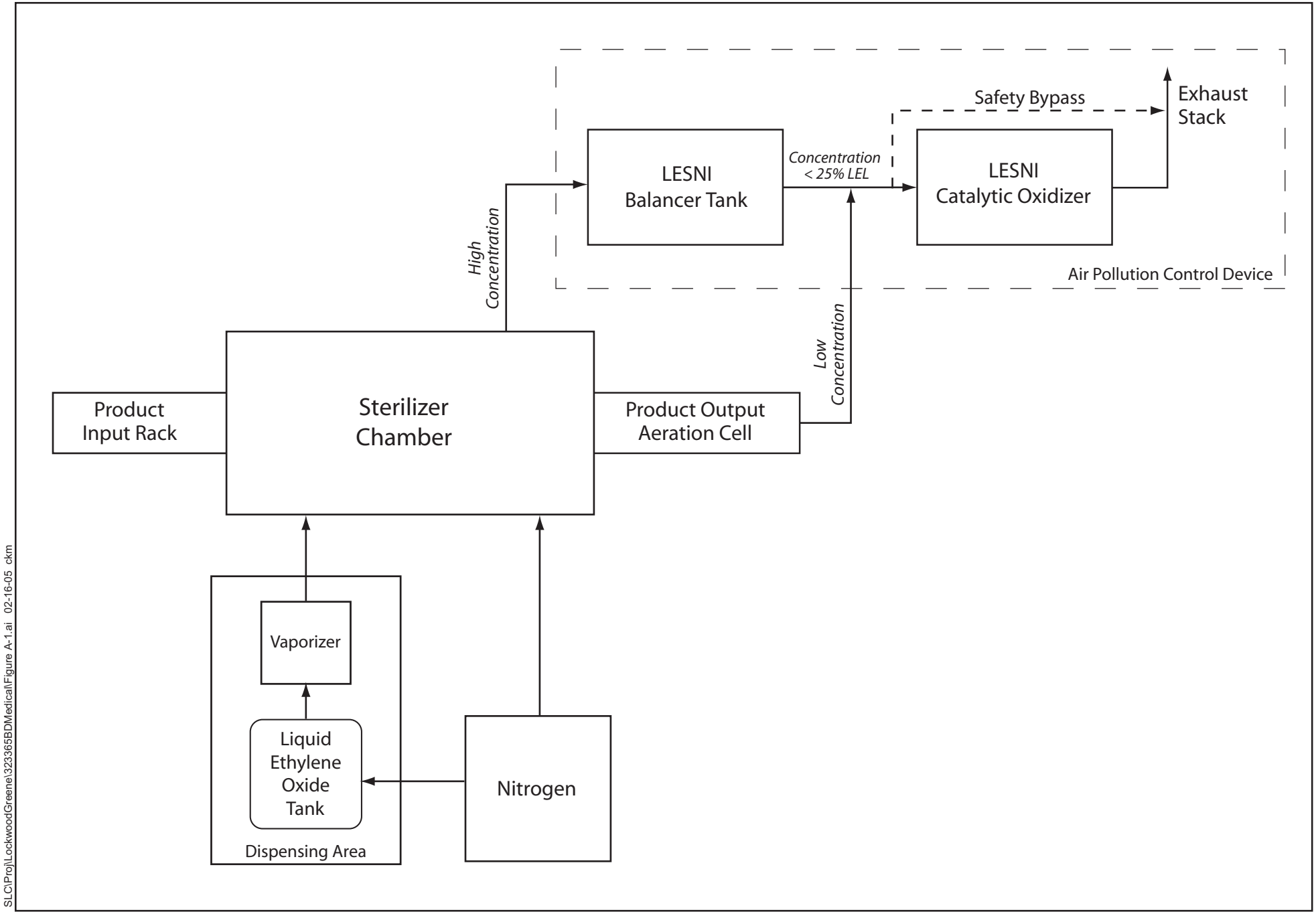


FIGURE A-1
Ethylene Oxide Sterilization Process Schematic

FORM 1.3 - PLANT LAYOUT DIAGRAM

COMPANY/FACILITY NAME: **BD Medical -** Pharmaceutical Systems DATE:
FACILITY ID#: 73007

Please provide a current Plant Layout Diagram (Plant Diagram) in the space below (Use back of this form and additional pages if necessary) or on a separate attached sheet(s). The Plant Diagram must include all stacks/emission points identified in Forms 2.0 and 3.0, as appropriate. Stacks/emission points and unit numbers must be cross-referenced between this Plant Diagram and the above Forms. In addition, the Plant Diagram should indicate the heights and locations of all buildings/structures and property boundaries. If a separate attached sheet(s) is (are) used (e.g., engineering diagrams, surveyor's drawing, etc.), it (they) should be clearly marked as being a replacement for Form 1.3.

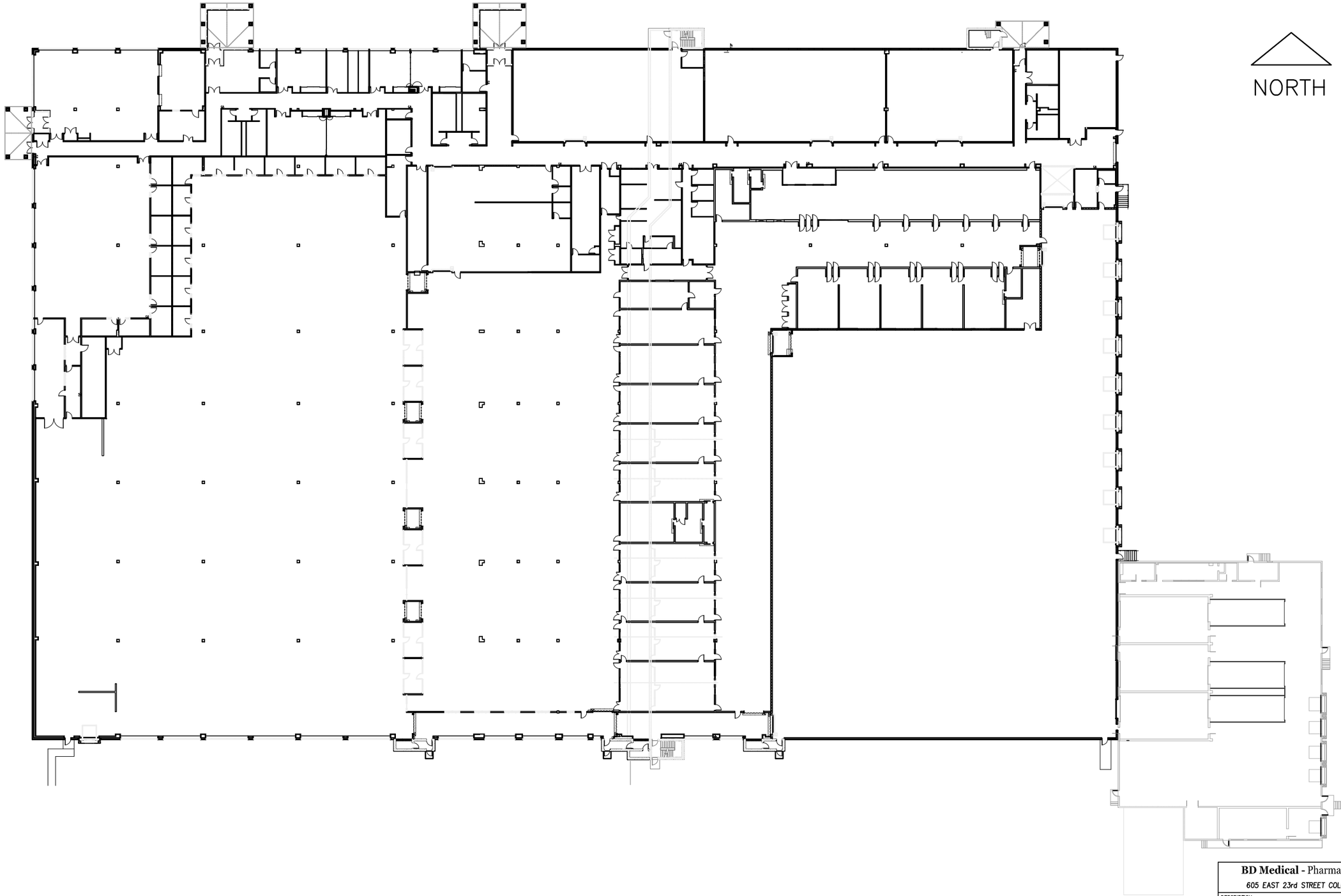
Please see enclosed attachment.

DUPLICATE THIS FORM AS NEEDED

FORM 1.3 - PLANT LAYOUT DIAGRAM

ADDITIONAL DIAGRAM SPACE

DUPLICATE THIS FORM AS NEEDED



NORTH

BD Medical - Pharmaceutical Systems

605 EAST 23rd STREET COLUMBUS, NEBRASKA 68601

DESCRIPTION:

FLOOR PLAN

NOTE:	DR. BY: GERMAN	DATE: 04/12/2005
	REV. # 00	SCALE: NONE

FORM 2.0 - PROCESS INFORMATION

COMPANY/FACILITY NAME: **BD Medical -** Pharmaceutical Systems DATE:
NDEQ FACILITY ID#: 73007

IMPORTANT: INSTRUCTIONS ON BACK OF FORM, PLEASE READ

MATERIAL PROCESS				FINAL PRODUCT	
PROCESS NUMBER	TYPE OF MATERIAL	CAPACITY (LBS/HR)	CAPACITY (TON/YR)	PRODUCT DESCRIPTION	CAPACITY (TON/YR)
100	Ethylene Oxide		228	---	---
				---	---

EQUIPMENT		INPROCESS FUEL DATA		
PROCESS NUMBER	PROCESS EQUIPMENT USED	TYPE OF FUEL BURNED	CAPACITY (AMT/HOUR)	CAPACITY (AMT/YEAR)
100	ETO Sterilizer/LENSI	Natural Gas	1,440 ft^3/hr	525,000 ft^3/yr
101	Emergency Generator	Diesel	46.4 gal/hr	13,920 gal/yr

STACK DATA						AIR POLLUTION CONTROL EQUIPMENT		
PROCESS NUMBER	HEIGHT	TOP INSIDE DIAMETER	STACK DISCHARGE	EXIT VELOCITY OF GAS	EXIT TEMP. OF GAS	TYPE CONTROL EQUIPMENT	% EFFI-CIENCY	DATE INSTALLED
100	52 ft	1.6 ft	7,060 CFM	72.5 ft/sec	55 °C	Cat. Ox.	99.9 %	At time of const. N/U
	ft	ft		ft/sec	°C		%	N/U
	ft	ft		ft/sec	°C		%	N/U
	ft	ft		ft/sec	°C		%	N/U
	ft	ft		ft/sec	°C		%	N/U

DUPLICATE THIS FORM AS NEEDED

INSTRUCTIONS: FORM 2.0 - PROCESS INFORMATION

PLEASE SUBMIT ANY ADDITIONAL INFORMATION PERTINENT TO EMISSION CONTROL SUCH AS FLOW RATES, EFFICIENCY OF CONTROL EQUIPMENT, TYPE OF CONTROL EQUIPMENT, OUTPUT LOADING, PERFORMANCE STANDARDS, MANUFACTURERS GUARANTEES, ETC.

FORMS CS, 1.0, 1.1, 1.2 AND 1.3 MUST BE SUBMITTED WITH THIS FORM

1. Please provide all of the information requested in the application.
2. COMPANY/FACILITY NAME, DATE and NDEQ FACILITY ID#: Enter the legal name of the company/facility as it appears on FORM 1.0, the date of the application and the facility ID# that has been assigned by the NDEQ. If this is a new plant, leave blank.

MATERIAL PROCESSES

3. PROCESS NUMBER: Use the number that this process is known by at this facility. Cross reference with the facility process diagram (FORM 1.2).
4. TYPE OF MATERIAL: Provide the raw material(s) that is(are) used for this process.
5. CAPACITY (lbs/hr): Enter the maximum amount of material that can be fed through this process in pounds per hour.
6. CAPACITY (ton/yr): Enter the total maximum amount of material that can be fed though this process, on an annual basis, in tons per year.

FINAL PRODUCT

7. PRODUCT DESCRIPTION: Provide a brief description of the product that is produced by this process.
8. CAPACITY (ton/year): Enter the total maximum amount of product that can be produced by this process on an annual basis.

EQUIPMENT

9. PROCESS NUMBER: Use the number that this process is known by at this facility. Cross reference with the processes listed above, if applicable, and the facility process diagram (FORM 1.2)
10. PROCESS EQUIPMENT USED: Give a brief description of the equipment that is used in this process. Cross reference the equipment with the facility process diagram (FORM 1.2).

INPROCESS FUEL DATA

11. TYPE OF FUEL BURNED: Enter the fuel used in this process. Enter NA if no fuel is used.
12. CAPACITY (AMT/HOUR): Enter the maximum amount of fuel that can be burned per hour in this process.
13. CAPACITY (AMT/YEAR): Enter the maximum amount of fuel that can burned on an annual basis.

STACK DATA

14. PROCESS NUMBER: Use the number that this process is known by at this facility. Cross reference with the processes listed above, if applicable, and the facility process diagram (FORM 1.2)
15. HEIGHT: Enter the height of the stack in feet.
16. TOP INSIDE DIAMETER: Provide the inside diameter of the stack at the top. If the stack does not have a circular opening, the equivalent diameter must be calculated and provided. The equivalent diameter of a square or rectangular stack can be calculated using the following equation: $\left(d_e = \left\{ \sqrt{\frac{area}{\pi}} \right\} * 2 \right)$ where d_e = equivalent diameter; *area* = area of the square or rectangle; and π = pi (3.14159).
17. STACK DISCHARGE: Indicate if the stack discharge is vertical, horizontal, or downward and whether a rain cap or other obstruction will be used.
18. EXIT VELOCITY OF GAS: Provide the maximum exit velocity of the gas from the stack in feet per second.
19. EXIT TEMPERATURE OF GAS: Provide the maximum exit temperature of the gas in degrees centigrade.

AIR POLLUTION CONTROL EQUIPMENT

20. TYPE CONTROL EQUIPMENT: Provide the control equipment utilized for this process. Cross reference the control equipment with the processes listed above, if applicable, and the facility process diagram (FORM 1.2).
21. EFFICIENCY: Provide the efficiency of the control equipment utilized for this process (If efficiency is not known, please note paragraph in bold at the top of the page.).
22. DATE INSTALLED: Provide the date the control equipment for this process was installed. Indicate if the equipment was new (N) or used (U) when installed.

FORM 3.0 - FUEL COMBUSTION DATA

COMPANY/FACILITY NAME: **BD Medical -** Pharmaceutical Systems DATE:_____
NDEQ FACILITY ID#: 73007

IMPORTANT: INSTRUCTIONS ON BACK OF FORM, PLEASE READ.

FUEL BURNING UNIT DATA				FUEL DATA		
UNIT NUMBER	CAPACITY (BTU/HR)	TYPE UNIT*	TYPE FUEL(S) BURNED	CAPACITY (AMT/HOUR)	HRS USED PER YEAR	CAPACITY (AMT/YR)
100/ETO Sterilizer		ETO Sterilizer	Natural Gas	1,440 ft^3/hr	x 8,760	525,600 ft^3/yr
					x 8,760	
101/Diesel Emergency Generator	600 kW	Diesel Engine	Diesel	46.4 gal/hr	x 8,760	13,920 gal/yr
					x 8,760	
					x 8,760	
					x 8,760	
					x 8,760	
					x 8,760	

* Boiler, Turbine, Diesel Engine, Duel Fuel Engine, Dryer, etc.

INSTALLATION DATE: UNIT#_____ DATE_____ UNIT#_____DATE_____
UNIT#_____ DATE_____ UNIT#_____DATE_____

IF BOILER BURNS FUEL OIL, LIST UNIT NUMBERS WHICH ARE:
HORIZONTALLY FIRED_____
TANGENTIALLY FIRED_____

IF COAL IS BURNED, IDENTIFY UNIT NUMBER(S) AND TYPE OF FURNACE:_____

STACK DATA N/A						AIR POLLUTION CONTROL EQUIPMENT		
PROCESS NUMBER	HEIGHT	TOP INSIDE DIAMETER	STACK DISCHARGE	EXIT VELOCITY OF GAS	EXIT TEMP. OF GAS	TYPE CONTROL EQUIPMENT	% EFFI-CIENCY	DATE INSTALLED
	ft	ft		ft/sec	°C		%	N/U
	ft	ft		ft/sec	°C		%	N/U
	ft	ft		ft/sec	°C		%	N/U
	ft	ft		ft/sec	°C		%	N/U
	ft	ft		ft/sec	°C		%	N/U

COAL DATA				FUEL OIL DATA			
%ASH	%SULFUR	HEAT CONTENT	SOURCE	GRADE	%SULFUR	HEAT CONTENT	SOURCE

DUPLICATE THIS FORM AS NEEDED

INSTRUCTIONS: FORM 3.0 - FUEL COMBUSTION DATA

PLEASE SUBMIT ANY ADDITIONAL INFORMATION PERTINENT TO EMISSION CONTROL SUCH AS FLOW RATES, EFFICIENCY OF CONTROL EQUIPMENT, TYPE OF CONTROL EQUIPMENT, OUTPUT LOADING, PERFORMANCE STANDARDS, MANUFACTURERS GUARANTEES, ETC.

FORMS CS, 1.0, 1.1, 1.2 AND 1.3 MUST BE SUBMITTED WITH THIS FORM

1. Please provide all of the information requested in the application.
2. COMPANY/FACILITY NAME, DATE and NDEQ FACILITY ID#: Enter the legal name of the company/facility as it appears on FORM 1.0, the date of the application and the facility ID# that has been assigned by the NDEQ. If this is a new plant, leave blank.

FUEL BURNING UNIT DATA

3. UNIT NUMBER: Enter the unit number as it is known at this facility. Cross reference with the facility process diagram (FORM 1.2).
4. CAPACITY: Enter the maximum capacity of the unit in BTU per hour.
5. TYPE UNIT: Enter the type of unit, i.e., Boiler, Turbine, Diesel Engine, Dual Fuel Engine, Dryer, etc.
6. TYPE FUEL(S) BURNED: Enter the type, or types, of fuel that will be burned by this unit.

FUEL DATA

7. CAPACITY (AMT/HOUR): Enter the maximum amount of fuel that can be burned per hour. Enter the amount for each fuel type.
8. HRS USED PER YEAR: Enter the total number of hours that the unit is used each year.
9. CAPACITY (AMT/YEAR): Enter the total amount of fuel that is consumed on an annual basis.

INSTALLATION DATE

10. For each unit listed provide the date it was installed at this facility.

IF BOILER BURNS FUEL OIL, LIST UNIT NUMBERS WHICH ARE:

11. For each unit that is horizontally fired enter the unit number in the appropriate space. For each unit that is tangentially fired enter the unit number in the appropriate space.

IF COAL IS BURNED, IDENTIFY UNIT NUMBER(S) AND TYPE OF FURNACE

12. List each unit that burns coal and provide the type of furnace that is being used.

STACK DATA

13. PROCESS NUMBER: Use the number that this process is known by at this facility. Cross reference with the processes listed above, if applicable, and the facility process diagram (FORM 1.2)
14. HEIGHT: Enter the height of the stack in feet.
15. TOP INSIDE DIAMETER: Provide the inside diameter of the stack at the top. If the stack does not have a circular opening, the equivalent diameter must be calculated and provided. The equivalent diameter of a square or rectangular stack can be calculated using the following equation: $\left(d_e = \left\{ \sqrt{\frac{area}{\pi}} \right\} * 2 \right)$ where d_e = diameter; *area* = area of the square or rectangle; and π = pi (3.14159).
16. STACK DISCHARGE: Indicate if the stack discharge is vertical, horizontal, or downward and whether a rain cap or other obstruction will be used.
17. EXIT VELOCITY OF GAS: Provide the maximum exit velocity of the gas from the stack in feet per second.
18. EXIT TEMPERATURE OF GAS: Provide the maximum exit temperature of the gas in degrees centigrade.

AIR POLLUTION CONTROL EQUIPMENT

19. TYPE CONTROL EQUIPMENT: Provide the control equipment utilized for this process. Cross reference with the processes listed above, if applicable, and the facility process diagram (FORM 1.2).
20. % EFFICIENCY: Provide the efficiency of the control equipment utilized for this process (If efficiency is not known, please note paragraph in bold at the top of the page.).
21. DATE INSTALLED: Provide the date the control equipment for this process was installed. Indicate if the equipment was new (N) or used (U) when installed.

COAL DATA

22. %ASH: Enter the percent by weight of ash in the coal.
23. %SULFUR: Enter the percent by weight of sulfur in the coal with appropriate units of measure.
24. HEAT CONTENT: Enter the heat content of the coal.
25. SOURCE: Enter where the coal came from.

FUEL OIL DATA

26. GRADE: Enter the grade of the of fuel oil being burned e.g., #1 Fuel oil, #2 Fuel oil, etc.
27. %SULFUR: Enter the percent by weight of sulfur in the fuel with appropriate units of measure.
28. HEAT CONTENT: Enter the heat content of the fuel.
29. SOURCE: Enter where the fuel came from.

APPENDIX B

RACT/BACT/LAER Clearinghouse Review

TABLE B-1
Search Results from the RBLC Database for EtO Sterilization Chamber Vents

ID/Company	Control Equipment	Emission Limits	Comments
CT-0136/United States Surgical Corporation	Catalytic Oxidizer	99.9% Efficiency 3 ppm emission limit	For Vent, Exhaust Chamber
CT-0137/United States Surgical Corporation	Catalytic Oxidizer	99.9% Efficiency 3 ppm emission limit	For Vent, Exhaust Chamber
CT-0111/United States Surgical Corporation	Catalytic Oxidizer	99.9% Efficiency 3 ppm emission limit	For Vent, Exhaust Chamber

TABLE B-2
Search Results from the RBLC Database for Diesel Emergency Generators

ID/Company	Control Equipment	Emission Limits	Comments
IA-0067/Midamerican Energy Company	Good Combustion Practices for all pollutants	Specific to each pollutant	Generator – 1,788 HP
TX-0407/Steag Power LLC	No Add-on Controls	Specific to each pollutant	Generator – 1,350 HP
OK-0072/Redbud Energy LP	No Add-on Controls	Specific to each pollutant	Generator – 1,818 HP

APPENDIX C

Emissions Calculations

BD Medical - Pharmaceutical Systems
ETO Emissions Calculations

Daily ETO Usage:	515	kg/day	Lesni Design
Worst case ETO Usage:	567	kg/day	with 10% contingency over Lesni design
Operation:	365	days/yr	
Annual ETO Usage:	455,855	lb/yr	
Annual ETO Emissions (uncontrolled):	455,855	lb/yr	Assume 100% ETO converted to emissions
% Removal for CatOx	99.9		
Annual ETO Emissions (controlled):	456	lb/yr	

BD Medical - Pharmaceutical Systems
Emergency Generator Emissions Calculations

NO_X Emission Factor (lb/HP-hr)	0.013	[AP-42, Table 3.4-1, Diesel Fuel]
CO Emission Factor (lb/HP-hr)	0.0055	[AP-42, Table 3.4-1, Diesel Fuel]
PM Total Emission Factor (lb/HP-hr)	0.0007	[AP-42, Table 3.4-1, Diesel Fuel]
SO_2 Emission Factor (lb/HP-hr)	0.0004	[AP-42, Table 3.4-1, Diesel Fuel]
TOC Emission Factor (lb/HP-hr)	0.0007	[AP-42, Table 3.4-1, Diesel Fuel]
Sulfur Content of Diesel Fuel	0.05	percent

	Generator
Engine Rating (kW)	600
Engine Rating (HP)	804.6
Annual Hours of Operations (hrs/yr)	300
NO_X Emissions (lb/yr)	3,137.94
CO Emissions (lb/yr)	1,327.59
PM Total Emissions (lb/yr)	168.97
SO_2 Emissions (lb/yr)	97.64
VOC Emissions (lb/yr)	170.17
NO_X Emissions (tpy)	1.57
CO Emissions (tpy)	0.66
PM Total Emissions (tpy)	0.08
SO_2 Emissions (tpy)	0.05
VOC Emissions (tpy)	0.09

HAP Emissions

Pollutant	Emission Factor (lb/MMBTU)	Generator Emissions (lb/yr)
Benzene	7.76E-04	4.76E-01
Toluene	2.81E-04	1.72E-01
Xylenes	1.93E-04	1.18E-01
Propylene	2.79E-03	1.71E+00
Formaldehyde	7.89E-05	4.84E-02
Acetaldehye	2.52E-05	1.55E-02
Acrolein	7.88E-06	4.83E-03
Naphthalene	1.30E-04	7.97E-02
Acenaphthylene	9.23E-06	5.66E-03
Acenaphthene	4.68E-06	2.87E-03
Fluorene	1.28E-05	7.85E-03
Phenanthrene	4.08E-05	2.50E-02
Anthracene	1.23E-06	7.54E-04
Fluoranthene	4.03E-06	2.47E-03
Pyrene	3.71E-06	2.27E-03
Benz(a)anthracene	6.22E-07	3.81E-04
Chrysene	1.53E-06	9.38E-04
Benzo(b)fluoranthene	1.11E-06	6.81E-04
Benzo(k)fluoranthene	2.18E-07	1.34E-04
Benzo(a)pyrene	2.57E-07	1.58E-04
Indeno(1,2,3-cd)pyrene	4.14E-07	2.54E-04
Dibenz(a,h)anthracene	3.46E-07	2.12E-04
Benzo(g,h,l)perylene	5.56E-07	3.41E-04

HAP Emission factors from AP-42, Tables 3.3-2.
Conversion Factors:
1 HP-hr = 0.00254 MMBTU

BD Medical - Pharmaceutical Systems
Emissions Calculations from Natural Gas combustion in the Lesni

Natural Gas Heating Value (BTU/scf)	1,000	
NO_X Emission Factor (lb/10^6scf)	50	[AP-42, Table 1.4-1, Small Boilers < 100 MMBTU/hr, with Low NO_X Burners]
CO Emission Factor (lb/10^6scf)	84	[AP-42, Table 1.4-1, Small Boilers < 100 MMBTU/hr]
PM Total Emission Factor (lb/10^6scf)	7.6	[AP-42, Table 1.4-2]
SO_2 Emission Factor (lb/10^6scf)	0.6	[AP-42, Table 1.4-2]
VOC Emission Factor (lb/10^6scf)	5.5	[AP-42, Table 1.4-2]

	Lesni
Natural Gas Usage (scf/hr)	1,440
Natural Gas Usage (10^6scf/hr)	0.0014
Annual Hours of Operations (hrs/yr)	8,760
NO_X Emissions (lb/yr)	631
CO Emissions (lb/yr)	1,060
PM Total Emissions (lb/yr)	96
SO_2 Emissions (lb/yr)	7.6
VOC Emissions (lb/yr)	69
NO_X Emissions (tpy)	0.32
CO Emissions (tpy)	0.53
PM Total Emissions (tpy)	0.05
SO_2 Emissions (tpy)	0.00
VOC Emissions (tpy)	0.03

Notes:
Emissions factors for the small boiler were used to estimate emissions for the Lesni

HAP Emissions

Pollutant	Emission Factor (lb/10^6scf)	Lesni Emissions (lb/yr)
2-Methylnaphthalene	2.40E-05	3.03E-04
3-Methylchloranthene	1.80E-06	2.27E-05
7,12-Dimethylbenz(a)anthracene	1.60E-05	2.02E-04
Acenaphthene	1.80E-06	2.27E-05
Acenaphthylene	1.80E-06	2.27E-05
Anthracene	2.40E-06	3.03E-05
Benza(a)anthracene	1.80E-06	2.27E-05
Benzene	2.10E-03	2.65E-02
Benzo(a)pyrene	1.20E-06	1.51E-05
Benzo(b)fluoranthene	1.80E-06	2.27E-05
Benzo(g,h,I)perylene	1.20E-06	1.51E-05
Benzo(k)fluoranthene	1.80E-06	2.27E-05
Butane	2.10E+00	2.65E+01
Chrysene	1.80E-06	2.27E-05
Dibenzo(a,h)anthracene	1.20E-06	1.51E-05
Dichlorobenzene	1.20E-03	1.51E-02
Ethane	3.10E+00	3.91E+01
Fluoranthene	3.00E-06	3.78E-05
Fluorene	2.80E-06	3.53E-05
Formaldehyde	7.50E-02	9.46E-01
Hexane	1.80E+00	2.27E+01
Indeno(1,2,3-cd)pyrene	1.80E-06	2.27E-05
Naphthalene	6.10E-04	7.69E-03
Pentane	2.60E+00	3.28E+01
Phenanathrene	1.70E-05	2.14E-04
Propane	1.60E+00	2.02E+01
Pyrene	5.00E-06	6.31E-05
Toluene	3.40E-03	4.29E-02
Arsenic	2.00E-04	2.52E-03
Barium	4.40E-03	5.55E-02
Beryllium	1.20E-05	1.51E-04
Cadmium	1.10E-03	1.39E-02
Chromium	1.40E-03	1.77E-02
Cobalt	8.40E-05	1.06E-03
Copper	8.40E-04	1.06E-02
Manganese	3.80E-04	4.79E-03
Mercury	2.60E-04	3.28E-03
Molybdenum	1.10E-03	1.39E-02
Nickel	2.10E-03	2.65E-02
Selenium	2.40E-05	3.03E-04
Vanadium	2.30E-03	2.90E-02
Zinc	2.90E-02	3.66E-01
Lead	0.0005	6.31E-03

HAP Emission Factors from AP-42, Tables 1.4-2, 1.4-3 and 1.4-4

BD Medical - Pharmaceutical Systems
Emissions Summary

	Generator	Lesni	ETO Unit	Total Project PTEs	Current PTEs	Post Project PTEs
NO_X Emissions (tpy)	1.57	0.32		1.88	35.81	37.69
CO Emissions (tpy)	0.66	0.53		1.19	5.15	6.34
PM_{10} Total Emissions (tpy)	0.08	0.05		0.13	0.79	0.92
SO_2 Emissions (tpy)	0.05	0.004		0.05	0.18	0.23
VOC Emissions (tpy)	0.09	0.03		0.12	14.93	15.05
HAP Emissions (tpy)	0.001	0.07	0.23	0.30	1.38	1.68

LESNI A/S
Air Purification Engineering
Kornmarken 7 • DK-7190 Billund

BD Medical - Pharmaceutical Systems
920 East 19th Street
Columbus
NE 68601
USA

Date: 2005-02-28
Our case: 04180

Your ref.:

Our ref.: NB/nb

Attn Mr. Mark German.

Subject: BD – EO abatement plant for Columbus.

Dear Mark German,

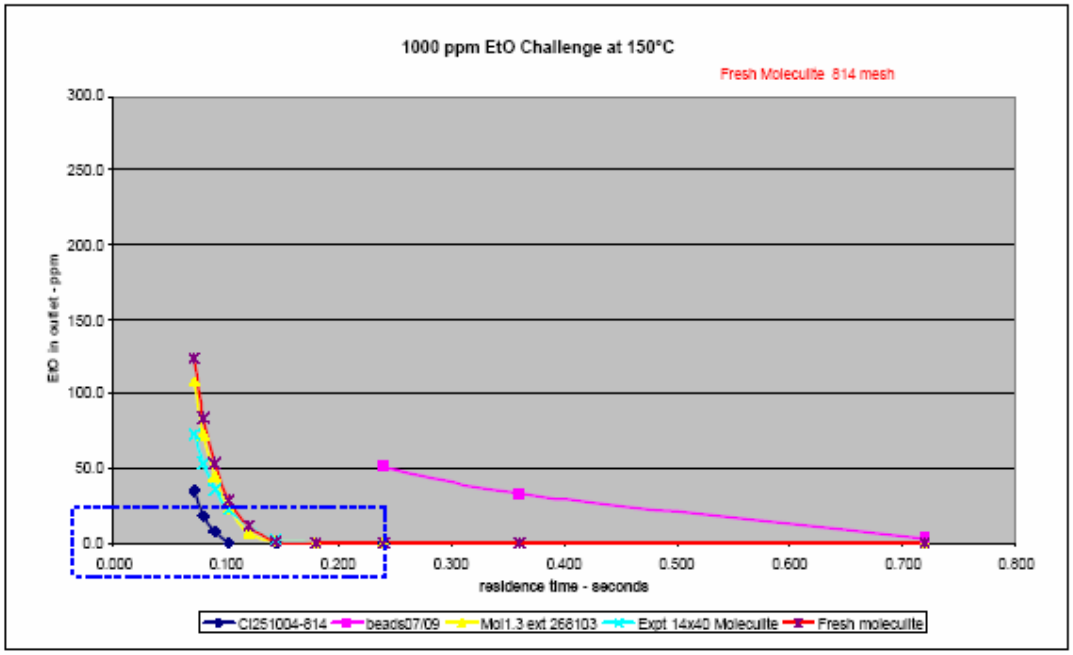
Referring you re request in e-mail of 24th February we hereby can confirm following statement:

Te EO Catalytic Oxidizing System with lay-out and set up as agreed in the project "EO Abatement Plant for Columbus" will after final installation and running in have an removal efficiency better than 99.9 %.

On the curve shown below the conversion efficiency of the catalyst is shown.

Best Regards
LESNI A/S

Niels Blaesbjerg



ARC CHEMICAL DIV BALCHEM CORP. -- ETHYLENE OXIDE -- 6830-00-291-5007

========== Product Identification ==========

Product ID:ETHYLENE OXIDE
MSDS Date:12/15/1992
FSC:6830
NIIN:00-291-5007
MSDS Number: BJYGW
=== Responsible Party ===
Company Name:ARC CHEMICAL DIV BALCHEM CORP.
Address:RTE 6 & 284
Box:180
City:SLATE HILL
State:NY
ZIP:10973
Country:US
Info Phone Num:914-355-2891 914-355-6314(FAX)
Emergency Phone Num:914-355-2891 800-424-9300(CHEMTREC)
Preparer's Name:GEORGE VAIL
CAGE:BALCH
=== Contractor Identification ===
Company Name:ARC CHEMICAL DIV BALCHEM CORP.
Address:RTE 6 & 284
Box:180
City:SLATE HILL
State:NY
ZIP:10973
Country:US
Phone:914-355-2891 800-424-9300(CHEMTREC)
CAGE:BALCH

========== Composition/Information on Ingredients ==========

Ingred Name:ETHYLENE OXIDE (SARA 302/313) (CERCLA)
CAS:75-21-8
RTECS #:KX2450000
Fraction by Wt: 100%
Other REC Limits:NONE RECOMMENDED
OSHA PEL:1 PPM; SEE 1910.1047
ACGIH TLV:1 PPM, A2; 9495
EPA Rpt Qty:10 LBS
DOT Rpt Qty:10 LBS

========== Hazards Identification ==========

LD50 LC50 Mixture:ORAL LD50 (RAT) IS 72 MG/KG
Routes of Entry: Inhalation:YES Skin:YES Ingestion:YES
Reports of Carcinogenicity:NTP:YES IARC:YES OSHA:YES
Health Hazards Acute and Chronic:EYES:MAY CAUSE SEVERE
IRRITATION,CORNEAL INJURY(POSSIBLY PERMANENT).SKIN:LIQUID MAY CAUSE
FROSTBITE AND SEVERE IRRITATION.MAY BE DERMALLY ABSORBED IN HARMFUL
AMOUNTS.INGEST:MAY CAUSE SEVERE GI TRACT I RRITATION.INHAL:MAY
CAUSE RESPIRATORY IRRITATION AND CNS DEPRESSION.CHRONIC:SEE SUPPL
DATA.
Explanation of Carcinogenicity:CONTAINS E [75-21-8] WHICH
IS LISTED BY NTP AND IARC AND REGULATED BY OSHA AS A CARCINOGEN.
Effects of Overexposure:SKIN:(REACTIONS MAY BE
DELAYED)BLISTERING,BURNS,EDEMA,VESCICLE FORMATION,SEVERE
DERMATITIS.SKIN
ABSORPTION:HEADACHE,DIZZINESS,NAUSEA,VOMITING.INHAL:HEADACHE,VOMITI
NG,CYANOSIS,DROWSINESS,WEAKNESS,INCOO RDINATION,SALIVATION,LABORED
BREATHING.INGEST:(UNLIKELY ROUTE OF ENTRY)ABDOMINAL
PAIN,NAUSEA,VOMITING.
Medical Cond Aggravated by Exposure:PERSONS WITH PRE-EXISTING

SKIN,LIVER,KIDNEY,ADRENAL,NERVE OR RESPIRATORY AILMENTS MAY BE AT INCREASED RISK FROM EXPOSURE.

========== First Aid Measures ==========

First Aid:SKIN:REMOVE CONTAMINATED CLOTHING;WASH WITH SOAP AND WATER.GET MEDICAL ATTENTION.EYES:FLUSH WITH WATER FOR 15 MINUTES.INHAL:REMOVE TO FRESH AIR.GIVE OXYGEN OR ARTIFICIAL RESPIRATION IF NEEDED.GET MEDI CAL ATTENTION.INGEST:DO NOT INDUCE VOMITING.GET PROMPT QUALIFIED MEDICAL ATTENTION.

========== Fire Fighting Measures ==========

Flash Point Method:TCC
Flash Point:<0F,<-18C
Autoignition Temp:Autoignition Temp Text:804F
Lower Limits:3
Upper Limits:100
Extinguishing Media:SMALL FIRES:CARBON DIOXIDE,DRY CHEMICAL.LARGER FIRES:POLYMER OR ALCOHOL FOAM.
Fire Fighting Procedures:USE A SELF-CONTAINED BREATHING APPARATUS AND FULL PROTECTIVE EQUIPMENT.COOL FIRE EXPOSED CONTAINERS WITH WATER FOG.FLUSH AREA WITH WATER AFTER FIRE EXTINGUISHED
Unusual Fire/Explosion Hazard:**FLAMMABLE - EXPLOSIVE** FIRE CONDITIONS MAY EVOLVE TOXIC FUMES.

========== Accidental Release Measures ==========

Spill Release Procedures:**ETHYLENE OXIDE GAS LEAK IS AN EMERGENCY** USE PROPER RESIRATORY AND PROTECTIVE EQUIPMENT.ELIMINATE SOURCES OF IGNITION.EVACUATE AREA.CALL 800-424-9300(CHEMTREC).
Neutralizing Agent:NOT APPLICABLE.

========== Handling and Storage ==========

Handling and Storage Precautions:STORE IN A COOL,DRY,WELL-VENTILATED PLACE.KEEP CONTAINER CLOSED WHEN NOT IN USE.KEEP AWAY FROM HEAT,SPARKS,FLAMES AND INCOMPATIBLE MATERIALS.
Other Precautions:DO NOT WEAR CONTACT LENSES.AVOID BREATHING VAPORS.AVOID SKIN AND EYE CONTACT.

========== Exposure Controls/Personal Protection ==========

Respiratory Protection:WHERE ENVIRONMENTAL CONTROLS ARE LACKING OR IN ENCLOSED SPACES USE A SELF-CONTAINED BREATHING APPARATUS.
Ventilation:USE EXPLOSION-PROOF LOCAL EXHAUST(LABORATORY FUME HOOD).
Protective Gloves:IMPERVIOUS
Eye Protection:CHEMICAL SPLASH GOGGLES
Other Protective Equipment:PROTECTIVE CLOTHING,AS NEEDED.PROVIDE A LOCAL EYE WASH STATION AND SAFETY SHOWER.
Work Hygienic Practices:WASH HANDS.SEPERATE WORK CLOTHES FROM STREET CLOTHES.LAUNDER WORK CLOTHES BEFORE REUSE.KEEP FOOD OUT OF THE WORK AREA.
Supplemental Safety and Health
TO SUPRESS VAPORS USE 100:1(WATER:ETHYLENE OXIDE).CHRONIC HEALTH HAZARDS:SKIN-SENSITIZATION;EYES-CATARACT FORMATION;INHAL-CHROMOSOMAL ABERRATIONS,PERIPHERAL NEUROTOXIC EFFECTS,NUMBING OF THE SENSE OF SMELL;INGEST-ANEMIA,LIVER,ADRENAL AND KIDNEY DAMAGE.

========== Physical/Chemical Properties ==========

HCC:G8
Boiling Pt:B.P. Text:51.0F,10.6C
Vapor Pres:1094

Vapor Density:1.5
Spec Gravity:0.871
pH:7
Evaporation Rate & Reference:72 (N-BUTYL ACETATE=1)
Solubility in Water:COMPLETE
Appearance and Odor:GAS/LIQUID;COLORLESS;SWEET ETHER-LIKE ODOR(ODOR THRESHOLD=700PPM)

========== Stability and Reactivity Data ==========

Stability Indicator/Materials to Avoid:YES
SELF-POLYMERIZING CATALYSTS(EG.K,SNCL(ANH),AL,FE,ALCOHOLS,MERCAPTANS,CU,OXIDES OF ALUMINUM OR IRON).
Stability Condition to Avoid:TEMPERTURES ABOVE 85F,SOURCES OF IGNITION.EXPLOSIVELY DECOMPOSES ABOVE 800F.
Hazardous Decomposition Products:CARBON DIOXIDE,CARBON MONOXIDE
Conditions to Avoid Polymerization:SELF-POLYMERIZING CATALYSTS(EG.K,SNCL(ANH),AL,FE,ALCOHOLS,MERCAPTANS,CU,OXIDES OF ALUMINUM OR IRON).

========== Disposal Considerations ==========

Waste Disposal Methods:DISPOSE OF IN ACCORDANCE WITH FEDERAL,STATE AND LOCAL REGULATIONS.RCRA CODE IS U115.

APPENDIX D

Regulatory Review Table

TABLE D-1
Part 63 Subpart A General Provisions Applicability to Sources using 10 Tons or More of Ethylene Oxide

Reference
63.1- Applicability
63.1(a)(1)
63.1(a)(2)
63.1(a)(3)
63.1(a)(4)
63.1(a)(6)
63.1(a)(7)
63.1(a)(8)
63.1(a)(10)
63.1(a)(11)
63.1(a)(12)-(14)
63.1(b)(1)-(2)
63.1(c)(1)
63.1(c)(2)
63.1(c)(4)
63.1(e)
63.2- Definitions
63.3- Units and abbreviations
63.4- Prohibited activities and circumvention
63.4(a)(1)-(4)
63.4(a)(5)
63.4(b)
63.4(c)
63.5- Preconstruction review and notification requirements
63.5(b)(1)
63.5(b)(4)
63.5(b)(5)
63.5(b)(6)
63.5(d)(3)-(4)
63.5(e)
63.6- Compliance with standards and maintenance requirements
63.6(a)(1)

TABLE D-1
Part 63 Subpart A General Provisions Applicability to Sources using 10 Tons or More of Ethylene Oxide

Reference
63.6(f)(2)(i)
63.6(f)(2)(iii)-(iv)
63.6(f)(3)
63.6(g)
63.6(i)(1)-(14)
63.6(i)(16)
63.6(j)
63.7- Performance testing requirements
63.7(a)(1)
63.7(a)(2)
63.7(a)(3)
63.7(b)
63.7(c)
63.7(d)
63.7(e)
63.7(f)
63.7(g)(1)
63.7(g)(3)
63.7(h)
63.8- Monitoring requirements
63.8(a)(1)
63.8(a)(2)
63.8(a)(4)
63.8(b)(1)
63.8(b)(2)
63.8(c)(1)(iii)
63.8(c)(2)-(3)
63.8(d)
63.8(e)(1)
63.8(e)(2)
63.8(e)(3)
63.8(e)(4)

TABLE D-1
Part 63 Subpart A General Provisions Applicability to Sources using 10 Tons or More of Ethylene Oxide

Reference
63.8(e)(5)(i)
63.8(f)(1)-(5)
63.8(g)(1)
63.8(g)(3)-(5)
63.9- Notification requirements
63.9(a)
63.9(b)(1)(i)
63.9(b)(2)-(3)
63.9(c)
63.9(e)
63.9(g)(1)
63.9(h)(1)-(3)
63.9(h)(1)-(3)
63.9(h)(6)
63.9(i)
63.9(j)
63.10- Recordkeeping and reporting requirements
63.10(a)
63.10(b)(1)
63.10(b)(2)(ii)
63.10(b)(2)(vi)-(xii)
63.10(b)(2)(xiv)
63.10(c)(1)
63.10(c)(5)
63.10(c)(8)
63.10(c)(10)-(13)
63.10(c)(14)
63.10(d)(1)
63.10(d)(2)
63.10(d)(4)
63.10(e)(1)
63.10(e)(1)(i)

TABLE D-1
Part 63 Subpart A General Provisions Applicability to Sources using 10 Tons or More of Ethylene Oxide

Reference
63.10(e)(2)(i)
63.10(e)(3)(i)-(iv)
63.10(e)(3)(vi)-(viii)
63.10(f)
63.11- Control device requirements
63.12- State authority and delegations
63.13- Addresses of State air pollution control agencies and EPA Regional Offices
63.14- Incorporations by reference
63.15- Availability of information and confidentiality